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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,903	10/08/2004	Yasumichi Hitoshi	7946-79831-01	1730

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EXAMINER	
NATARAJAN, MEERA	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,903	HITOSHI ET AL.	
	Examiner	Art Unit	
	Meera Natarajan	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42 and 45-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42 and 45-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. The amendment filed 12/14/2007 is acknowledged and entered into the record. Accordingly, claims 23, 36-41, 43 and 44 have been canceled and new claims 45-50 have been added.

3. Claims 42 and 45-50 are pending and will be examined on the merits.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claim 42 is rejected under 35 U.S.C. 102(a) as being anticipated by Folias et al. (Human Molec. Genetics, Vol. 11(21), pp.2591-2597, 2002).

6. Claim 42, is drawn to a method that has 2 active steps: (1) contacting a compound with Fanconi anemia group A protein (FANCA) polypeptide with 100% identity to SEQ ID NO:6 and (2) determining the effect of the compound upon the FANCA polypeptide activity or expression as compared to a control without the

compound. "Effect" is defined in the specifications (p. 21) as changes in a characteristic of a FANCA polypeptide, e.g., changes in ligand or substrate binding activity".

7. Folias et al. teaches that contacting FANCA with BRCA1 results in ligand binding; therefore Folias et al. teaches the same active steps as applicant's claimed method. As evidence by the specification the "effect" being determined is ligand binding of the test compound, BRCA1, to the FANCA polypeptide. Folias et al. teach the FANCA polypeptide which s 100% identical to SEQ ID NO: 6 (as evidence by the references cited in Folias et al.) One of ordinary skill in the art would readily envisage that the "effect", as defined by the specification, of FANCA without the test compound, as in a control assay, would result in no ligand binding of BRCA1 to FANCA and thus a change in the "effect", defined as ligand binding of the FANCA polypeptide to BRCA1, would occur. The reference teaches each and every limitation of the claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 42 and 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Folias et al. in view of Khanna et al. (Nature, Vol. 27, pp.247-254, 2001), Okamura et al. (Oncology Research, Vol. 11(6), pp.281-285, 1999) and El-Deiry et al. (WO.1999/050280).

11. The claims are drawn to a method of identifying a compound that induces cell cycle arrest by (1) contacting a compound with Fanconi anemia group A protein (FANCA) polypeptide with 100% identity to SEQ ID NO:6 and (2) determining the effect of the compound upon the FANCA polypeptide activity or expression as compared to a control without the compound. Cell cycle arrest is determined by measuring aldehydes dehydrogenase activity and assaying DNA synthesis.

12. The teachings of Folias et al. have been presented in the 102(a) rejection set forth above. Folias et al. teach the active steps performed by the method recited in Claim 23 but does not teach the "effect" upon the cell as cell cycle arrest and determining this effect by measuring aldehydes dehydrogenase activity and DNA synthesis. These deficiencies are made up for by Khanna et al., Okamura et al. and El-Deiry et al.

13. Khanna et al. teach cells respond to DNA damage by activating a complex DNA-damage-response pathway that includes cell-cycle arrest, the transcriptional and post-

transcriptional activation of a subset of genes including those associated with DNA repair (see Abstract).

14. Okamura et al. teach genes related to cell cycle regulation, cell respiration and cytoskeletal structure. Okamura et al. disclose Aldehyde dehydrogenase as one of the genes involved in cell cycle regulation.

15. El-Deiry et al. teach assays and compositions for identifying compounds that enhance or repress cellular proliferation via BRAC1 mediated pathways. El-Deiry et al. disclose methods comprising cell lines with or without an agent and assaying for apoptosis or cell cycle arrest, using standard methods such as TUNEL assay or BrdU (an analogue of thymidine) incorporation assay to measure DNA synthesis (see p. 27 and Example 1 and 2). El-Deiry et al. disclose the use of green fluorescent proteins as reporter genes used in the cell cycle arrest assays disclosed (see p. 22).

16. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to determine the effect of BRCA1 upon FANCA by measuring cell cycle arrest using methods that measure aldehydes dehydrogenase and DNA synthesis using thymidine incorporation of GFP. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in Folias et al., Khanna et al., Okamura et al., and El-Deiry et al. Folias et al. suggest FANCA and BRCA1 interaction directly connects BRCA1 to the FA pathway of DNA repair (see last sentence of Abstract). Khanna et al. teach DNA repair as a result of DNA damage induces cell cycle arrest. Okamura et al. and El-Deiry et al. disclose methods for measuring cell cycle arrest, such as measuring aldehydes dehydrogenase

activity and DNA synthesis. Therefore, it would have been obvious to one of skill in the art to contact BRCA1 and FANCA, as taught in Folias et al., and measure cell cycle arrest by performing the assays taught in Okamura et al. and El-Deiry et al. because Folias et al. disclose BRCA1 and FANCA direct interaction is involved in DNA repair and Khanna et al. teach DNA repair is involved in inducing cell cycle arrest.

All other rejections set forth in the office action mailed 04/02/2007 are withdrawn in view of the applicant's amendments and arguments.

Conclusion

17. Claims 42 and 45-50 are rejected.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meera Natarajan whose telephone number is 571-270-3058. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER